K011365

OCT 2 6 2001

SECTION 16
510(k) SUMMARY

Submitted by: Island Critical Care Corp.
9 Myrtle Street
Stratford, Prince Edward Island
C1B 1P4
Tel: (902) 569-4447, Fax: (902) 569-4406
www.spo2.com

Company Contact: Sean P. Flanigan, Vice President & COO

Date Summary Prepared: May 1, 2001

Trade Name: VitalSAT™ Pulse Oximeter

Common Name: Pulse Oximeter

Classification Name: Oximeter (74DQA) (870.2700)

Substantially Equivalent Device: Masimo SET® 2000 Pulse Oximeter and accessories
510(k) Number – K990966

Description of the VitalSAT™ Pulse Oximeter

The VitalSAT™ Pulse Oximeter is a device incorporating Masimo SET® technology and consisting of a stand alone monitor, Masimo connecting cable, and Masimo LNOP oximetry sensors to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The monitor consists of two LED displays on either side of a liquid crystal display. The LED to the left of the liquid crystal display displays the SpO_2 value and the LED to the right displays the pulse rate. The liquid crystal display displays the pulse plethysmographic waveform, user information, trending data and configuration data.

Features

- An automatic self-test at start-up.
- Dual, brightly lit seven segment LED displays (red and green)
- Backlit display for excellent visibility in subdued lighting conditions.
- Direct access to user-selectable high and low alarm limits for SpO_2 and pulse rate.
- An audible pulse indicator with an adjustable volume.
- Audible (adjustable volume) alarms.
- An alarm-silence feature; silences audible alarms continuously or for 120 second intervals.
- Status and alarm informational messages appear on the LCD.
- 2,4,8, 10,12, 14, or 16 second SpO_2 response averaging modes.
- Trend data storage of up to eight (8) days.
- Compatible with several types of the Masimo LNOP® sensors for flexibility.
- Automatic scaled plethysmographic waveform.

510(k) SUMMARY

The PC series of connecting cables connects the monitor to the oximetry sensors and transfers LED drive power to the oximetry sensors from the monitor and the monitor receives the detector signals from the oximetry sensor.

The LNOP® series of oximetry sensors measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently than unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

Intended use
The VitalSAT™ Pulse Oximeter is intended for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile and home environments.

Indications for Use
The VitalSAT™ Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The VitalSAT™ Pulse Oximeter is indicated for adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are poorly perfused in hospitals, hospital-type facilities, mobile and home environments.

Principles of Operation
The principles of operation of the VitalSAT™ Pulse Oximeter and the predicate device are that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because a oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET® technology incorporated into the VitalSAT™ Pulse Oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation into the Masimo SET® software. The values in the look-up table are based upon human blood studies conducted by Masimo Corporation against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and non-motion conditions.

Method of Operation
The VitalSAT™ Pulse Oximeter is turned on. An oximetry sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the VitalSAT™ pulse oximeter module.

510k SUMMARY

The monitor will begin continuously displaying the patient's pulse plethysmographic waveform, pulse rate, and SpO_2 value. The practitioner can adjust the high and low alarm limits to their desired value, if required. The practitioner can then use the information that is continuously displayed on the
monitor, and hear if an alarm limit is reached, to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the oximetry sensor is removed (and disposed of it is a single use device), and the power to the monitor is turned off.

Power Source
The VitalSAT™ Pulse Oximeter is powered with a voltage input of 100-240 Vac, 50-60 Hz or with a sealed gel cell battery with an operating time of seven (7) hours and a charge time of less then eight (8) hours.

Specifications and Operating Ranges

Range

Saturation (% SpO_2)	1% - 100%
Pulse Rate (bpm)	25 –240
Perfusion	0.02% - 20%

Accuracy

Saturation (% SpO_2) – During Motion Conditions[1]	
Adults, Pediatrics	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% -100% ± 3 digits
	0% - 69% unspecified
Saturation (% SpO_2) – During Motion Conditions [2,3]	
Adults, Pediatrics[2]	70% - 100% ± 3 digits
	0% - 69% unspecified
Neonates[3]	70% -100% ± 3 digits
	0% - 69% unspecified
Pulse Rate (bpm) – During No Motion Conditions[1]	
Adults, Pediatric, Neonates	25 to 240 ± 3 digits
Pulse Rate (bpm) – During Motion Conditions[2,3]	
Adults, Pediatric, Neonates	25 to 240 ± 5 digits

Resolution

Saturation (% SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance[4]

> 0.02% Pulse Amplitude and % Transmission > 5%	Saturation (% SpO_2) ± 2 digits Pulse Rate ± 3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings

Power

Voltage Input Range	85-265 Vac, 8 – 18 Vdc 50/60 Hz
Maximum AC Power Consumption:	24 VA

Fuses

.25 X .25 1A 3AG/250V

Isolation

Chassis Leakage Current	Less than 100 µAmp
Ground resistance	Less than 1.0 Ω

Environmental

Operating Temperature	-5°C to +35°C
Storage Temperature	-20°C to +60°C
Relative Humidity	5% to 95% noncondensing

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of default parameters
Automatic alarm messages
Trend data output of Sp02, pulse rate – up to 8 days of stored data

Displays

Type	Backlit LCD Screen
Pixels	240 x 64 dots
Dot Pitch	0.53 mm
Data Displayed	Plethysmographic wave, Alarms, Trends, Status messages
Type	Red LED
Data Displayed	SpO_2 Value (%)

Type Green LED

510(K) SUMMARY

Data Displayed Heart rate

Audio indicators
Adjustable volume audible pulse: OFF and 20% to 100% in 5 steps
Adjustable volume audible alarm tone: levels and 20% to 100% in 5 steps
Alarm silence (120 seconds); all mute (continuous silence)
Pulse rate out-of-limits alarm
SpO_2 level out-of limits alarm
Sensor condition alarms
System failure and recharge-battery alarms

Models
Averaging mode: 4,6,8,10,12,14, and 16 seconds
Sensitivity Normal and High

Audible alarms
Alarm 20% to 100% in 5 steps
Pulse Beep OFF and 20% to 100% in 5 steps

COM 1: A digital interface for network communication.
Data output every second; date, time, SpO_2, and pulse rate
9600 Baud bi-directional
Number of bits per character: 8
Parity None
Bits 1 start,1 stop
Handshaking None
Connector type 9-pin standard D, female
Connector pin functions:
No Connection
Receive data – RS-232 ±9V (±5 Vmin)
Transmit data – RS-232 ±9 V (±5 V min)
No Connection
Signal Ground Reference for COM 1 signals
No Connection
Request to send – Not used
Clear to send – Not used
No Connection

Dimensions
Height 3.1 in (7.8 cm)
Width 11.2 in (28.25 cm)
Depth 7.6 in (19.2 cm)
Weight6.5 lbs (2.95 kg)

510(K) SUMMARY

The VitalSAT™ Pulse Oximeter have been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and the VitalSAT™ simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus on standard deviation encompasses 68% of the population.

Technological characteristics of the VitalSAT™ Pulse Oximeter compared to the Masimo SET® 2000 Pulse Oximeter and Accessories (K990966).

The technological characteristics of the VitalSAT™ Pulse Oximeter and Accessories and the Masimo SET® 2000 Pulse Oximeter and Accessories (K990966) both have the same or similar technological characteristics in design, materials, and energy source.

The design of both devices is the same in that both devices are stand alone devices that monitor the functional oxygen saturation of arterial hemoglobin (SpO_2 sensor) for adult, pediatric, and neonatal patients. The principles of operation and methods of operation for both devices is the same.

The materials used in both devices are similar. The instrument cases are formed of thermoplastic materials. The electronics within the instruments are standard electronic parts (resistors, capacitors, integrated circuits, wiring, connectors, etc.). The sensors and cables for both devices are formed of thermoplastic materials, adhesives, wires, electrical contacts, light emitting diodes, and photo detectors.

The VitalSAT™ Pulse Oximeter operates under 85-265VAC 50/60 Hz while the Masimo SET® 2000 Pulse Oximeter and Accessories (K990966) operates under 120 VAC 60 Hz. The VitalSAT™ Pulse Oximeter can also operate under external battery power. The VitalSAT™ Pulse Oximeter utilizes an internal rechargeable sealed lead acid battery while the Masimo SET® 2000 Pulse Oximeter and Accessories (K990966) utilizes a rechargeable sealed gel cell battery.

Environmental Testing

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions – November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact duration (,>24 hr to 30 days) as defined ISO-10993-1: 1992 Biological Evaluation of Medical Devices – Part 1: Guidance on Selection of Tests. All patient contacting material **passed.**

Nonclinical tests performed that support a determination of substantial equivalence.

The VitalSAT™ Pulse Oximeter and Accessories was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

The results of the bench testing showed that the VitalSAT™ Pulse Oximeter and Accessories returned the same saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits when compared to the simulators used.

Conclusions

The results of the **environmental testing** demonstrated that the VitalSAT™ Pulse Oximeter and Accessories **met** the requirements of Reviewers Guidance for Premarket Submissions – November 1993.

The results of the **biocompatibility testing** demonstrates the all patient contacting material **met** the requirements of ISO-10993-1: 1992 Biological Evaluation of Medical Devices – Part 1: Guidance on Selection of Tests for Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days).

The results of the **bench testing** demonstrates that the VitalSAT™ Pulse Oximeter **meets** its performance requirements.

The **testing** performed demonstrates that the VitalSAT™ Pulse Oximeter is safe, effective, and performs as well as the predicate device, the Masimo SET® 2000 Pulse Oximeter and Accessories (K990966), and therefore, it is substantially equivalent to the Masimo SET® 2000 Pulse Oximeter and Accessories (K990966).

1. The Masimo SET® 2000 Pulse Oximeter & LNOP® series of Sensors and Cables has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2, against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. The VitalSAT™ incorporates the same hardware and software as the predicate device and as such replicates these values.

2. The Masimo SET® 2000 Pulse Oximeter & LNOP® series of Sensors and Cables has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2, against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. The VitalSAT™ incorporates the same hardware and software as the predicate device and as such replicates these values.

3. The Masimo SET® 2000 Pulse Oximeter & LNOP® Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. The VitalSAT™ incorporates the same hardware and software as the predicate device and as such replicates these values.

4. The Masimo SET® 2000 Pulse Oximeter & LNOP® series of Sensors and Cables has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and The Island Critical Care simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. The VitalSAT™ incorporates the same hardware and software as the predicate device and as such replicates these values.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Mr. Sean P. Flanigan
Island Critical Care Corp.
9 Myrtle Street
Stratford, P.E.I., C1B 1P4
CANADA

Re: K011365
VitalSAT™ Pulse Oximeter Model IC32000
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: 74 DQA
Dated: August 10, 2001
Received: August 10, 2001

Dear Mr. Flanigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

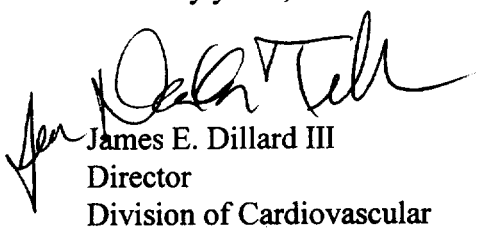
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 – Indications for Use

510(k) Number (if known): K011365

Device Name: VitalSAT™ Pulse Oximeter

Indications For Use:

The VitalSAT™ Pulse Oximeter is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The VitalSAT™ Pulse Oximeter is indicated for adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are poorly perfused in hospitals, hospital-type facilities, mobile and home environments.

Contraindications For Use:

The VitalSAT™ Pulse Oximeter is contraindicated for use as an apnea monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011365

Prescription Use ✓
(Per 21 CFR 801.109)

Or

Over-The-Counter Use _____
(Optional Format 1-2-96)
